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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard C. Ewers

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EXAMINER

HAND, MELANIE JO

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/612,109	Applicant(s) EWERS ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-10,12,46-56 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,8-10,12,46-56 and 58-60 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see Remarks, page 7, filed October 16, 2008, with respect to the rejections under 35 U.S.C. 102 and 35 U.S.C. 103 relying upon the Ewers reference have been fully considered and are persuasive. The rejections of claims 1, 3-5, 8-10, 12, 46, 48-53, 55, 56, 58-60 under 102r as anticipated by Ewers and claims 2, 47 and 54 under 35 U.S.C. 103 as unpatentable over Ewers have been withdrawn.
2. Applicant's arguments with respect to the claim rejections under 35 U.S.C. 103 relying upon the combined teaching of Martin and Hayhurst, alone or in combination with additional references, have been fully considered but they are not persuasive. With respect to arguments under heading A.1: The coil disclosed by Martin is one embodiment of element 102. Martin discloses in paragraph 0059, cited in the rejection of claim 1, that element 102 is slidable (i.e. translatable) with respect to suture strands 104/106. Since the axis of the suture strands is parallel to the axis of the lumen of delivery tube 200, and the sutures themselves are placed within tube 200, the coil 250 serving as element 102 as disclosed by Martin is certainly also translatably disposed within the lumen of tube 200.
3. With respect to arguments under heading A.2: The devices of Martin and Hayhurst both clearly involve delivering sutures to a surgical site. In order to deliver a suture either delivered by or within a needle, the suture needs to reach the site. Therefore, some axial sliding or other translation must necessarily take place to deliver the suture from the needle to the site where it is needed. Hayhurst explicitly teaches this feature where this feature, though certainly fairly suggested by Martin, is absent from the Martin disclosure. It is examiner's position that one of ordinary skill in the art would certainly be motivated to employ a feature from a structurally

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similar or identical device that accomplishes the common purpose of the two devices.

Therefore, since both the Martin device and Hayhurst device involve delivering a suture (immediately or inevitably) to a site, and the Hayhurst device discloses a translation motion of a needle within a tube needed or desired to accomplish this goal of delivering the suture, motivation certainly exists to modify the Martin device to have a needle translatably disposed within a tube as disclosed by Hayhurst that allows easier and expedited movement of the already translatable coil within the needle toward the site to deliver the suture. Examiner disagrees that the function of the element 102 (coil 250) disclosed by Martin as fastening element would be defeated; adding the additional translation of the needle within the tube would not interfere with the element's ability to fasten the suture.

4. Applicant's arguments under heading B with regard to dependent claims 2, 3, 5, 47 and 48 have been fully considered but are not persuasive, as applicant's arguments depend entirely on arguments presented under heading A.2, which have been addressed *supra*. Applicant additionally argues that the braided layer does not meet the limitation of a plurality of slots substantially perpendicular to the longitudinal axis of the tube. Applicant has not clearly defined "substantially perpendicular" and thus the claim was and is given its broadest reasonable interpretation. One of ordinary skill in the art can reasonably expect that a braid, especially a torqueable and flexible braid such as that suggested by Martin defining a tube, will bend or twist in such a manner that the slots between braid strands will change their angle so as to be substantially perpendicular to the longitudinal axis, e.g. the twisting motion that occurs in a torqueable tube. The "diamonds" defined between the filaments when the braid is bent or stretched are compressed when the tube is bent back or twisted to define slots.

5. As to arguments under heading C: Examiner explicitly stated motivation for providing the sharpened tip in the fastening device of Kortenbach from the Kortenbach reference itself,

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specifically that the tip as part of a screw arrangement, very similar to the coil's motion disclosed by Martin, facilitates tissue penetration and such a screw arrangement with a sharpened tip is well known in the art. Therefore, there certainly exists motivation to provide the coil of the device of Martin as modified by Hayhurst with a sharpened tip. The fact that the Martin device is intended to fasten sutures only further supports examiner's position that the sharpened tip is desirable, as sutures are useless to fasten tissue or close a wound, for example, if they never penetrate said tissue.

6. Applicant's arguments presented under heading D with regard to dependent claim 54 have been fully considered but are not persuasive, as applicant's arguments depend entirely on arguments under heading A.2, which have been addressed *supra*.

7. With respect to arguments under heading E: To clarify examiner's position, when sutures are being placed, one of ordinary skill in the art can reasonably expect the presence of fluid, especially blood, at the suture site, which can obstruct the desired site for placement of the structure or visibility in general. Therefore, while the Martin device is not explicitly concerned with fluid drainage as is the device of O'Keefe, the presence of slots aiding fluid flow into the tube could certainly aid in redirecting fluid away from the suture site, at least temporarily, to facilitate visibility and proper placement of the suture.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 9, 10, 12, 46, 51-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (U.S. Patent Application Publication No. 2003/0167071) in view of Hayhurst (U.S. Patent No. 6,656,182).

With respect to **claim 1**: Martin teaches a delivery catheter in the form of a catheter loading tool 200 for a gastric reduction system, the delivery catheter 200 comprising an elongate tube considered herein to be torqueable inasmuch as it can be rotated or bent by application of a force from the user, and flexible inasmuch as Martin teaches that the catheter is advanced through the vascular system which defines a nonlinear path, thus necessitating a flexible catheter. Delivery catheter 200 has a back end and a front end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of

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Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations “needle is translatably disposed within the tube” and “at least one anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle” obvious.

With respect to **claim 9**: The coil taught by Martin comprises a plurality of coils that form a central opening for the passage of the needle of the combined teaching of Martin and Hayhurst. The motivation to modify the device of Martin so as to include a needle is stated *supra* with respect to claim 1.

With respect to **claim 10**: The coil and needle of the combined teaching of Martin and Hayhurst are substantially coaxial inasmuch as they are both disposed within the tube and thus are concentric with the instant tube. The motivation to modify the device of Martin so as to include a needle is stated *supra* with respect to claim 1.

With respect to **claim 12**: The delivery catheter 520 of Martin further comprises a push rod 522. However the rod is not translatably disposed within a needle or adapted to push the anchor out of a distal end of the needle. Hayhurst teaches that the instant needle comprises a push rod in the form of hollow needle 16 translatably disposed within the needle and adapted to push the anchor 10 out of a distal end 26 of the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 46**: Martin teaches a catheter 200 comprising a flexible tube having a front end and a back end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least one anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle" obvious.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, towards the back end of the tube.

With respect to **claim 51**: The needle of the combined teaching of Martin and Hayhurst is positioned to extend out of the front end of the instant flexible tube and through the coil, as the coil is also disposed within the tube and defines an central opening for the needle. The motivation to modify the device of Martin so as to comprise a needle that is translatably disposed within the instant tube is stated *supra* with respect to claim 49.

With respect to **claim 52**: The delivery catheter 520 of Martin further comprises a push rod 522. However the rod is not translatably disposed within a needle or adapted to push the anchor out of a distal end of the needle. Hayhurst teaches that the instant needle comprises a push rod in the form of hollow needle 16 translatably disposed within the needle and adapted to push the anchor 10 out of a distal end 26 of the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 53**: The needle of the combined teaching of Martin and Hayhurst is considered herein to have a noncoring tip 26 inasmuch as the lumen of the tip either contains an anchor or push rod at any given time and thus is not functional to core the tissue.

With respect to **claim 55**: Martin teaches a catheter 200 comprising a flexible and torqueable tube having a front end and a back end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in

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said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least one anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle" obvious.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, towards the back end of the tube.

With respect to **claim 58**: The delivery catheter 520 of Martin further comprises a push rod 522. However the rod is not translatably disposed within a needle or adapted to push the anchor out of a distal end of the needle. Hayhurst teaches that the instant needle comprises a push rod in

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the form of hollow needle 16 translatably disposed within the needle and adapted to push the anchor 10 out of a distal end 26 of the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

With respect to **claim 59**: Martin teaches a catheter 200 comprising a flexible and torqueable tube having a front end and a back end and a handle attached adjacent to the back end of the tube, since catheter 200 is a loading tool that is advanced through the vascular system manually by a caregiver. ('071, 0058) Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin does not disclose the presence of a hollow needle within the tube having a piercing tip extendible out of the front end of the tube. Hayhurst teaches a tissue fastening device comprising a hollow needle 14 having a piercing tip 26 extending out of the front end of the device. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating

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tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least one anchor translatably disposed within the needle, and moveable out of the piercing tip of the needle" obvious.

Hayhurst teaches an anchor ejector in the form of a push rod 16 within the needle 14. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the instant delivery catheter comprises a push rod translatably disposed within a needle as taught by Hayhurst with a reasonable expectation of success.

Martin does not teach a needle control on the handle linked to the needle for moving the needle within the tube. However since the combined teaching of Martin and Hayhurst teaches a needle within the tube that is responsible for piercing or fastening tissue areas together, it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst so as to include a needle control on the handle linked to the needle to provide a means for controlling the movement and piercing action of the needle to the operator.

The combined teaching of Martin and Hayhurst discloses that the control of the anchor ejector lies in the pushing motion applied by the user at will. An anchor ejector control on the handle linked to the anchor ejector would simply be another, automated means of accomplishing the instantly disclosed manually completed task of controlling the motion of the anchor ejector. Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst so as to include an anchor ejector control on the handle linked to the anchor ejector, hollow needle/push rod 16, to provide an

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alternate automated means for controlling the motion of the needle/push rod, thus controlling the ejection of the anchors until they are needed.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, toward the handle.

With respect to **claim 60**: Martin teaches a catheter 200 comprising a flexible tube having a front end and a back end. Catheter 200 comprises a fastening element 102 comprising a coil 250 on a front end of a shaft that is translatably disposed within a lumen in said tube 200. The coil is able to be straightened out and thus is extendible out of the front end of the tube. (0058-0060,0062)

Martin teaches that the catheter/loading tool 200 is present in a kit along with a needle but does not teach that the needle is translatably disposed within the tube 200. Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin such that the needle is translatably disposed within the tube of loading tool/catheter 200 with a reasonable expectation of success.

Martin teaches an anchor but teaches that the anchor is fastening element 102 comprising the coil 250 and thus does not teach a separate anchor. Hayhurst teaches at least one anchor 10 is translatably disposed within the needle 14 and moveable out of the penetrating tip of the needle 14. ('182, Col. 6, lines 21-27) The motivation to combine the teachings of Martin and Hayhurst is stated *supra*. The device of the combined teaching of Martin and Hayhurst renders the limitations "needle is translatably disposed within the tube" and "at least

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one anchor translatably disposed within the needle, and moveable out of the penetrating tip of the needle” obvious.

The combined teaching of Martin and Hayhurst discloses a suture connected to one or more of the anchors, with the suture extending within the tube by extending within the needle which is within the tube, towards the back end of the tube.

10. Claims 2, 3, 5, 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claims 1 and 46 above, and further in view of Madrid et al (U.S. Patent Application Publication No. 2002/058905).

With respect to **claim 2**: Martin does not teach that the tube is formed of braided wire. Hayhurst teaches that the anchor member is formed of braided wire material but also does not teach a tube that the needle and anchor are disposed within a tube formed of braided wire as recited in claim 2. Madrid teaches that catheters formed of braided stainless steel are well known in the art, therefore it would be obvious to one of ordinary skill in the art to modify the device of Martin and Hayhurst such that the tube is formed of braided stainless steel with a reasonable expectation of success. ('905, 0046) Thus, the combined teaching of Martin and Hayhurst and Madrid renders the limitation “wherein the tube is formed of braided wire” obvious.

With respect to **claim 3**: The tube of the combined teaching of Martin and Hayhurst and Madrid is formed of braided wire and thus necessarily contains a plurality of slots disposed substantially perpendicular to a longitudinal axis of the tube. The motivation to modify the combined teaching of Martin and Hayhurst such that the instant tube is formed of braided wire is stated *supra* with respect to claim 2.

With respect to **claim 5**: The slot density of the combined teaching of Martin and Hayhurst and Madrid is increased near a distal end of the tube due to the presence of the braiding material when compared to the tube without the braided material. The motivation to modify the combined teaching of Martin and Hayhurst such that the instant tube is formed of braided wire is stated *supra* with respect to claim 2.

With respect to **claim 47**: The tube of catheter 200 of Martin is torqueable. Martin does not teach that the tube is formed of braided wire. Hayhurst teaches that the anchor member is formed of braided wire material but also does not teach a tube that the needle and anchor are disposed within a tube formed of braided wire as recited in claim 2. Madrid teaches that catheters formed of braided stainless steel are well known in the art. Therefore it would be obvious to one of ordinary skill in the art to modify the device of Martin and Hayhurst such that the tube is formed of braided stainless steel with a reasonable expectation of success. ('905, 0046) Thus, the combined teaching of Martin and Hayhurst and Madrid renders the limitation "wherein the tube is formed of braided wire" obvious.

With respect to **claim 48**: Applicant has not explicitly and clearly defined the phrase "substantially perpendicular" therefore the claim is given its broadest reasonable interpretation. The tube of the combined teaching of Martin and Hayhurst and Madrid is formed of braided wire and thus necessarily contains a plurality of slots disposed substantially perpendicular to a longitudinal axis of the tube. One of ordinary skill in the art can reasonably expect that a braid, especially a torqueable and flexible braid such as that suggested by Martin defining a tube, will bend or twist in such a manner that the slots between braid strands will change their angle so as

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to be substantially perpendicular to the longitudinal axis, e.g. the twisting motion that occurs in a torqueable tube. The “diamonds’ defined between the filaments when the braid is bent or stretched are compressed when the tube is bent back or twisted to define slots. The motivation to modify the combined teaching of Martin and Hayhurst such that the instant tube is formed of braided wire is stated *supra* with respect to claim 47.

11. Claims 8 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claims 1 and 46 above, and further in view of Kortenbach (U.S. Patent Application Publication No. 2003/0208211).

With respect to **claim 8**: Martin does not explicitly teach that the coil includes a sharpened distal tip. Hayhurst also does not teach a coil having a sharpened distal tip. Kortenbach teaches a coil tissue fastening device substantially identical in structure to the coil fastening element taught by Martin. As can be seen in any of the figures disclosed by Kortenbach the coil includes a sharpened distal tip. Kortenbach refers to this as a screw arrangement to facilitate tissue penetration for fastening the tissues together and teaches that such arrangement is known in the art. ('211, 0041) Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst such that the instant coil includes a sharpened distal tip as taught by Kortenbach with a reasonable expectation of success to ensure that the tissues are securely fastened together.

With respect to **claim 49**: Martin does not explicitly teach that the coil includes a sharp tip. Hayhurst also does not teach a coil having a sharpened distal tip. Kortenbach teaches a coil tissue fastening device substantially identical in structure to the coil fastening element taught by

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Martin. As can be seen in any of the figures disclosed by Kortenbach the coil includes a sharpened distal tip. Kortenbach refers to this as a screw arrangement to facilitate tissue penetration for fastening the tissues together and teaches that such arrangement is known in the art. ('211, 0041) Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Martin and Hayhurst such that the instant coil includes a sharp tip as taught by Kortenbach with a reasonable expectation of success to ensure that the tissues are securely fastened together.

The combined teaching of Martin and Hayhurst teaches a tissue anchoring device comprising a needle 14 having a penetrating tip 26 adjacent to the front end of the instant tube, namely the end closest to the tissue. Since the devices of Martin and Hayhurst seek to solve a similar problem in the art (i.e. deliver a suture and anchor to a tissue site for a surgical procedure), it would be obvious to one of ordinary skill in the art to modify the kit of Martin so as to comprise a needle 14 having a penetrating tip 26 adjacent to the front end of the instant tube with a reasonable expectation of success to more easily penetrate adjacent tissue.

12. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claim 46 above, and further in view of Iwami et al (U.S. Patent Application Publication No. 2002/0087098).

With respect to **claim 54**: The combined teaching of Martin and Hayhurst does not disclose a tube having a coating of fluorine resin. Iwami teaches coating a catheter with fluorine resin to act as a location marker for observation of the progress of the tube during endoscopy while the tube is in the body. Since Ewers teaches that the instant apparatus is used in gastrointestinal endoscopy, it would be obvious to one of ordinary skill in the art to modify the device of Martin

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such that the instant tube has a coating of fluorine resin as taught by Iwami to provide a mark on the tube to allow observation of the tube's progress during an endoscopy procedure with otherwise limited visibility. ('098, ¶¶0026,0034,0035,0102)

13. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Hayhurst ('182) as applied to claim 46 above, and further in view of O'Keefe (U.S. Patent No. 6,921,378).

With respect to **claim 56**: The combined teaching of Martin and Hayhurst does not disclose a tube having through slots. O'Keefe teaches a drainage catheter having a plurality of slots extending substantially perpendicular to a longitudinal axis of the tube and present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11) When sutures are being placed, one of ordinary skill in the art can reasonably expect the presence of fluid, especially blood, at the suture site, which can obstruct the desired site for placement of the structure or visibility in general. Therefore, while the Martin device is not explicitly concerned with fluid drainage as is the device of O'Keefe, the presence of slots aiding fluid flow into the tube would aid in redirecting fluid away from the suture site, at least temporarily, to facilitate visibility and proper placement of the suture. Therefore placing slots as disclosed by O'Keefe in the tube disclosed by Martin in the device of Martin as modified by Hayhurst would be obvious to one of ordinary skill in the art.

With regard to the limitation "to increase the flexibility of the tube", such limitation constitutes functional language that is given little patentable weight herein. Since the combined teaching of Martin and Hayhurst and O'Keefe renders the limitation of claim 56 as to a tube

having through holes, the combined teaching of Martin and Hayhurst and O'Keefe also renders the limitation "to increase the flexibility of the tube" obvious.

Allowable Subject Matter

14. Claim 4 is still objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761